

obviousness-type double patenting, responses to which are discussed below. Reconsideration of the present application in view of the above amendments and following remarks is respectfully requested.

**Rejection under 35 U.S.C. §112, 2<sup>nd</sup> Paragraph**

Claim 5 is rejected under 35 U.S.C. §112, second paragraph, as being indefinite since it recites a “non-aqueous” composition while the rest of the claims are directed to aqueous compositions.

Applicants respectfully question the assertion that the rest of the claims are directed to aqueous compositions. Claim 1 refers to a “particle-forming composition”, wherein a “particle-forming composition” is defined as a composition that is *capable of* forming particles upon contact with an aqueous medium. (emphasis added)(See Application, page 4, lines 17-19). Such a definition does not limit the compositions of claim 1 to aqueous compositions. Claim 2 specifically refers to “a composition of particles in an aqueous medium, wherein the particles comprise a modafinil compound.” While the composition of claim 2 is aqueous, the rejected claim 5 is dependant on claim 1, not claim 2. Hence, Applicant respectfully asserts that each claim is definite, and respectfully requests the rejection be withdrawn.

**Rejections under 35 U.S.C. §102(b)**

***Grebow ‘845 Patent:***

Claims 1-4, 6, 32-33, 36-37, 39, 41-44, 47-48, 51-52, and 54 are rejected under 35 U.S.C. §102(b) as being anticipated by Grebow et al. because it teaches compositions comprising modafinil particles, and it encompasses stable suspensions.

Applicants respectfully submits that Grebow does not teach particle-forming compositions as defined in the current application. The current application defines a “particle-forming composition” as a composition that is capable of forming particles upon contact with an aqueous medium. A “stable suspension” refers to a mixture of particles that remain intact and dispersed in a liquid medium such that the suspension can be stored and administered in a pharmaceutically acceptable manner. A “particle” or “particles” refers to substantially **non-crystalline structures**, preferably an aggregation of molecules in a discrete non-crystalline structure, such as a micelle, microsphere, droplet, colloid, or globule. (emphasis added)(See Application, page 4, lines 17-28). Grebow fails to disclose “particles” as they are defined in the instant application. Hence, not all elements of the current invention are disclosed by the reference, so the rejection is unsupported by the art, and reconsideration and withdrawal of the rejection under §102 is respectfully requested.

***Nguyen’347 Patent:***

Claims 1-4, 6, 11, 14-15, 32-33, 36-37, 39, 47, 51, and 54 are rejected under 35 U.S.C. §102(b) as being anticipated by Nguyen et al. because it teaches compositions comprising particles or microparticles of modafinil, and that it encompasses stable suspensions.

Applicants respectfully submit that, in an argument similar to that posited above, Nguyen fails to teach particle-forming compositions as defined in the current application. Hence, reconsideration and withdrawal of the rejection under §102 is respectfully requested.

**Rejection under 35 U.S.C. §103(a)**

Claims 17-18, 34-35, 38, 45-46, 49-50 and 53 are rejected under 35 U.S.C. §103(a) as being unpatentable over Grebow, et al., and claims 8-10, 13, 17-20, 34-35, 38, and 40-46 are

similarly rejected over Nguyen, et al. in view of Lafon.

Applicants respectfully submit that the references, either alone, or in combination, fail to teach the claimed invention. The instant claims involve particle-forming compositions and stable suspensions, as outlined in the above arguments. As discussed above, the reference(s) fail to teach or suggest said particle-forming compositions and stable suspensions.

Applicants further submit that Lafon does not cure the deficiencies of Nguyen. Hence, neither Grebow, nor Nguyen in view of Lafon teach the disclosure of the instant application, and as such the instant claims are non-obvious.

In view of the above amendments and remarks, reconsideration and withdrawal of the rejection under §103 is respectfully requested.

#### **Double Patenting Rejection**

Claims 1, 3-5, 14-15, 32-34 and 35 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-3, 7-8, 10-13, and 26-29 of copending Application No. 09/974,473.

Applicants await issuance of the patent resulting from the 09/974,473 application. Accordingly, Applicants will address this rejection upon further indication of allowable subject matter in the present application.

#### **Objections**

Claims 12, 16 and 21-31 are objected to as being dependent on a rejected base claim, but would be allowable if rewritten in independent form.

Applicants gratefully acknowledge that no prior art has been cited against the aforementioned claims. Applicants will address this objection upon indication of allowable

subject matter in the present application.

**Conclusion**

In view of the above, it is believed that all the claims are in form for allowance, and an early notification to that end is respectfully requested.

Respectfully submitted,



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